

AQUATO BABY- glycerin lotion **ItoB Co.,Ltd**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Glycerin

Water, Dimethicone, Butylene Glycol, etc

Skin Protectant - Moisturizing, Soothing

keep out or reach of the children

Dispense the right amount and gently apply onto entire face and body in accordance with the skin texture.

Allow product to be absorbed by skin.

1. Do not use in the following cases(Eczema and scalp wounds)

2.Side Effects

1)Due to the use of this drug if rash, irritation, itching and symptoms of hypersensitivity occur discontinue use and consult your pharmacist or doctor

3.General Precautions

1)If in contact with the eyes, wash out thoroughly with water If the symptoms are severe, seek medical advice immediately

2)This product is for external use only. Do not use for internal use

4.Storage and handling precautions

1)If possible, avoid direct sunlight and store in cool and area of low humidity

2)In order to maintain the quality of the product and avoid misuse

3)Avoid placing the product near fire and store out in reach of children

for external use only



AQUATO BABY

glycerin lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71567-0002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	6 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
WATER (UNII: 059QF0K00R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71567-0002-1	150 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/05/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part347	07/05/2017	

Labeler - ItoB Co.,Ltd (690099724)

Registrant - ItoB Co.,Ltd (690099724)

Establishment

Name	Address	ID/FEI	Business Operations
TAENAM MEDICOS CO., LTD		689846359	manufacture(71567-0002)

Establishment

Name	Address	ID/FEI	Business Operations
ItoB Co.,Ltd		690099724	pack(71567-0002) , label(71567-0002)